



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,147	01/29/2004	Andrics Jan Smit	34537US1	4624

116 7590 06/01/2007
PEARNE & GORDON LLP
1801 EAST 9TH STREET
SUITE 1200
CLEVELAND, OH 44114-3108

EXAMINER

BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
----------	--------------

3768

MAIL DATE	DELIVERY MODE
-----------	---------------

06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,147

Applicant(s)

SMIT ET AL.

Examiner

Etsub D. Berhanu

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 32-61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/29/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

1. Claim 60 is objected to because of the following informalities: "it" in line 2 should be amended to read - - the excitation radiation - -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 36, 51-54 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "preferably at an angle of about 45° relative to the irradiated surface of the skin" in lines 3-4 of claim 36 renders the claim indefinite because it is unclear whether the limitation is part of the claimed invention. The phrase "preferably at an angle of about 45° relative to said surface" in lines 6-7 of claim 51 renders the claim indefinite because it is unclear whether the limitation is part of the claimed invention. Claim 51 recites the limitation "the measuring window" in lines 4 and 5. There is insufficient antecedent basis for this limitation in the claim. Claim 52 recites the limitation "said measuring window" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 53 recites the limitation "said measuring window" in lines 1-2 and "the passage surface" in line 2. There is insufficient antecedent basis for these limitations in the claim. Further, it is unclear which surface is being referred to by the phrase "said surface" in line 2 of claim 53. Claims 54 and 58 recite the limitation "said measuring window" in lines 2 and 3. There is insufficient antecedent basis for these limitations in the claims.

Art Unit: 3768

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 32, 34-39, 47, 49-51, 53, 55-56 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Talmor'181 (cited by Applicant).

Figure 2 of Talmor'181 discloses a device and method for monitoring a tissue site using fluorescence, which includes a light source 28 that emits wavelengths between 400-450nm, a detector 18 that provides an image area of 1-100 cm², a measuring window 32 for receiving radiation from an irradiation window 30, wherein the second surface of the irradiation window is larger than the measuring window and wherein the measuring window is at an angle between 70 and 80 degrees relative to the surface of the skin (see also description of Figure 2). Talmor'181 also discloses an excitation radiation of 400-450nm and an emission radiation of 570-770nm (col. 4, lines 3-24). Regarding claims 55 and 56, Talmor'181 discloses that light source 28 is a xenon or mercury arc lamp with a filter (col. 4, lines 17-21).

6. Claims 32-33, 37-41, 43-45, 47-48, 51-57, 60 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Kollias et al.'059 (cited by Applicant).

Kollias et al.'059 discloses an instrument and method for measuring glucose concentrations by using fluorescence (see ABSTRACT). Figure 2 of Kollias et al.'059 discloses a light source 14 and a detector 18. Kollias et al.'059 discloses: an illumination area of 0.2 cm² (col. 5, lines 57-58); use of wavelengths in the range of 300-345 nm (col. 5, lines 27-32); a measuring window of detector 18 is held away from the surface of the skin since contact with the skin is made using optical fibers (see Figure 10A and col. 6, lines 51-53); an excitation wavelength of 420nm and an emission wavelength of 500 nm (col.

Art Unit: 3768

6, lines 46-67); reflected radiation being detected (see Figures 10A and 10B); multiple wavelengths in a normalizing section for determining glucose (col. 10, line 59 – col. 11, line 12), wherein normalizing one wavelength by using another wavelength is considered to be aggregating detected fractions of fluorescent radiation to an aggregated amount of detected electromagnetic radiation; ends of optical fibers (Figures 10A and 10B), wherein the ends include an irradiation and measuring window, and wherein the ends move relative to a measuring window of the detector which is located in the analyzing instrument, when the fiber is placed on the skin, the fiber and windows capable of being placed at an angle of 25-65 degrees relative to the skin surface; filters, lamps and laser diodes as light sources (col. 6, lines 25-28, col. 14, lines 1-10, col. 9, line 65 – col. 10, line 3); irradiation being changed when measuring a reflected and emission radiation (col. 13, line 66 – col. 14, line 47); an irradiation being performed in a pulse fashion (col. 9, line 6 – col. 10, line 12); different wavelengths being chosen using a wavelength selector (Figure 11, element 107 and col. 13, line 66 – col. 14, line 47); and control means (Figure 2, element 12) for controlling the excitation radiation of a light source, wherein the control means allows the apparatus to be capable of intermittently irradiating skin tissue and for separately detecting radiation from the skin tissue.

7. Claims 32, 41-42, 46-47, 53, 56, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al.'127 (cited by Applicant).

Anderson et al.'127 discloses a method and apparatus for delivering ultraviolet radiation for the analysis of skin (see ABSTRACT), the method and apparatus comprising: effected skin covering an area of 1cm^2 (col. 3, lines 11-12); use of illuminators (Figure 1, elements 14 and 34) which deliver ultraviolet radiation and a detector (Figure 1, element 22); detecting reflected and fluorescent radiation (col. 3, line 65 – col. 4, line 4); an array of detectors (col. 12, lines 14-16); a reference measurement made in the form of a spectrometer reflectance ratio (Figure 4, element 138); a lamp as a light source (col. 9, lines 34-38); a spectrometer (Figure 1, element 49); and separate detectors for detecting reflected excitation radiation and fluorescent radiation (col. 12, lines 22-32).

Art Unit: 3768

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB

ERIC F. WINAKUR
PRIMARY EXAMINER

